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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,819	01/13/2006	Hiroshi Okazaki	Q82144	3159
23373	7590	06/20/2011		
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER GUCKER, STEPHEN	
			ART UNIT 1649	PAPER NUMBER
			NOTIFICATION DATE 06/20/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

Office Action Summary	Application No. 10/564,819	Applicant(s) OKAZAKI, HIROSHI	
	Examiner STEPHEN GUCKER	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-24 and 27-64 is/are pending in the application.
- 4a) Of the above claim(s) 19-23 and 33-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-18, 24, 27-32 and 61-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/13/10, 8/26/10, 5/6/11</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. Applicant's amendment filed 2/26/10 has been entered and has obviated the grounds of rejection under 35 USC 112, 1st paragraph for not limiting the scope to bFGF and the 35 USC 102 rejection as being anticipated by Bansal. The 35 USC 112, 1st paragraph rejection is maintained for claim 7, and new rejections under 35 USC 112, 1st paragraph and 35 USC 103 are set forth in response to applicant's amendment. The Examiner has also noted the acceptance of the drawings filed January 13, 2006. Applicant mentions drawings filed September 14, 2006 and May 14, 2007; however, no such drawings for these dates are of record in this application.

2. Claims 19-23 and 33-60 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/27/09. Claims 8-9 and 25-26 have been canceled. Claims 1-7, 10-18, 24, 27-32 and new claims 61-64 are under examination.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 10-18, 24, 27-32, and 61-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 24 have been amended to include the phrase “and passaging and purifying the oligodendrocyte precursor cells in the medium” and support for such amendment has been indicated at paragraphs [0098]–[0100] and [0103]–[0105] of the specification. However, those portions of the specification teach a method where the oligodendrocyte precursor cells are incubated for one month in a medium C where they change from a bipolar morphology (A2B5(+)O4(-)) to multipolar morphology, which is characteristic of A2B5(+)O4(+)cells. When virtually all of the cells acquired a sun-like multipolar morphology and proliferating colonies arose in response to bFGF, these colonies of cells were trypsinized with medium B and were replated in a medium D (DMEM/B27; 15-30 ng/ml bFGF). The cells were trypsinized and replated every week and subculture was repeated indefinitely in a medium D. During the initial period of subculturing in a medium D, some of the cells gave rise to type 2 astrocytes, suggesting that this initial population of cells was still developmentally heterogeneous. Although proliferating A2B5(+)O4(+)cells were induced even in the next step, these non self-renewing cells differentiate into oligodendrocytes or cells of other phenotypes and died after the limited proliferation number and within a period of one month. After that, some self-renewing A2B5(+)O4(+) oligodendrocyte precursor cells were produced and started to proliferate in medium D. After approximately one month of subculturing in a medium D, type 2 astrocytes no longer appeared and more than a 99.99% homogenous population of O4(+)O1(-) oligodendrocyte precursor cells was established.

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Therefore, applicant's amendment of 2/26/10 introduces new matter into the claims because the specification discloses three different mediums (all lacking platelet-derived growth factor (PDGF)) that are used in the instant methods to achieve the recited limitation of obtaining a self-renewing, phenotypically homogenous population of oligodendrocyte precursor cells having a synchronized developmental stage, rather than a passaging and purifying step occurring in the medium as now recited in the instant methods. Furthermore, the actual passaging and purifying step takes place at least partially in a medium B that does not contain any bFGF (see paragraph [0102]). This is a new matter rejection.

4. Claims 7 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record and the following. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 7 recites that the homogeneous population of oligodendrocyte precursor cells are restricted to the oligodendrocyte lineage. However, as the prior art from Bansal et al. demonstrated (Bansal 1996 set forth below), a precursor cell's lineage is dependent upon its age and specific culturing conditions involving a specific pattern and amount of growth factors, and not the precursor cell itself, and the instant specification does not provide adequate guidance or direction to put such a cell as claimed into the hands of the public without undue experimentation.

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Applicant's arguments filed 2/26/10 have been fully considered but they are not persuasive. Applicant has amended claim 7 to depend upon claim 6, but the only antecedent basis for "said homogenous population of oligodendrocyte precursor cells" is found in claim 1 which claim 7 depended upon when the rejection was made, so the rejection of record stands. Furthermore, it is noted that A2B5(+)O4(-)O1(-)cells and A2B5(+)O4(+)O1(-)cells are not restricted to the oligodendrocyte lineage, but may differentiate into type 2 astrocytes (see paragraphs [036], [038], [098], and [0103]).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 10-11, 13-18, 24, 27-28, 30-32, 62, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bansal et al. 1996 (C4 of IDS filed 2/27/07; "Bansal 1996") in view of WO 97/44442 (C1 of IDS filed 8/13/10; "Johe").

Bansal teaches a method of culturing oligodendrocyte progenitors from neonatal rat telencephalon with 10 ng/ml of bFGF without PDGF to produce what Bansal calls "late progenitors" and mature oligodendrocytes (page 273). Bansal notes the synchronizing effects of bFGF, and late progenitors are mostly A2B5(+)O4(+)O1(-), but some are A2B5(+)O4(+)O1(+) (see pages 264-265 and Figure 1). With regards to claim 18, the prior art meets these limitations because the prior art cells "have the ability" to meet the limitations because the limitations are dependent on further culturing conditions as taught by the prior art and the instant disclosure.

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Similarly, the prior art meets the limitations of claim 2 because they “are culturable” for at least about one year without phenotypic change as long as they remain in a medium comprising bFGF and without PDGF. Bansal does not teach passaging and purifying the oligodendrocyte precursor cells in the medium comprising bFGF in the absence of PDGF or the use of precursor cells harvested from the spinal cord.

Johe does teach passaging and purifying *in vitro* cultures of stem cells in medium containing at least 10 ng/ml bFGF in the absence of PDGF derived from the spinal cord (pages 19-21) which can differentiate into oligodendrocytes (page 27).

It would have been obvious to one of ordinary skill in the art at the time of the invention to passage the progenitors of Bansal with the methods of Johe in order to increase the number of progenitors because the conditions of Johe permit mass expansion up to 10^9 fold in culture (page 38). In addition, Johe makes the explicit suggestion that his methods can be used with intermediate precursor cells (such as the progenitor cells of Bansal or the precursor cells of the instant invention), rendering the instant invention *prima facie* obvious (pages 42-43).

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is 571-272-0883. The examiner can normally be reached on Mondays through Fridays from 0930 to 1800.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. G./

Examiner, Art Unit 1649

Stephen Gucker

June 15, 2011

/Robert C. Hayes/

Primary Examiner, Art Unit 1649